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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,641	06/11/2001	Cato T. Laurencin	DRE-0055	2890
26259	7590	04/04/2006	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/878,641	LAURENCIN ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed January 23, 2006 has been entered. New claim 12 has been added. All pending claims 1-12 are being considered for further examination on the merits.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 6-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. (WO 95/01810 A1, as cited in applicant's IDS) in view of Chervitz (USPN 4,917,699 as cited in previous office action).

Wolowacz et al. discloses a replacement construct for tendons or ligaments with all the elements of claims 1, 2 and 12, but is silent to the braided scaffold being a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique. The ligament replacement (page 1, lines 3-5) includes a braided polymeric fiber-based (page 16, lines 32-35), slowly degradable scaffold (page 2, lines 5-11). The scaffold is seeded with cells (page 1, lines 27-30) using a method that implies that the scaffold is porous (page 17, lines 19-21). See page 8, lines 20-21 for the ingrowth of the cells being supported by the scaffold. Chervitz teaches a prosthetic ligament comprising a three-dimensional braided scaffold formed using a three-

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dimensional textile braiding technique in order for an individual strand of fiber to extend in all directions within the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 2, lines 43-49 and column 3, lines 1-27. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Chervitz to modify the standard braided scaffold of Wolowacz et al. to a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 1, lines 26-32 and 43-50.

Claim 3, see page 2, lines 1-3 for the cells being fibroblasts, which are mesenchymal in origin.

Claims 6 and 7, see page 1, lines 3-5 and page 5, lines 4-16 for a method of replacing a damaged ligament.

Claim 8, see pages 16-17, steps (a)-(c) of Example 1 for a method of producing a graft material composed of living cells in a degradable matrix comprising harvesting and culturing cells in a culture and seeding the cultured cells onto the scaffold of claim 1 by sucking cell suspension through the scaffold under vacuum.

Claim 9, see page 16, lines 18-20 for the cells being fibroblasts, which are mesenchymal in origin.

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With respect to claim 12, Wolowacz et al. is also silent to the replacement construct having two end sections for attachment of the replacement construct and a middle region differing from the two end regions in size, braiding angle, porosity and mechanical strength which promotes formation of ligament and tendon tissue. Chervitz teaches the prosthetic ligament (20) having two end sections (22, 32) that are capable of being used for attachment of the replacement construct (20) and a middle region (30). Because one end section (22) is formed around a mandrel (42) from a three-dimensionally braided flat panel, the other end section (32) is two-dimensionally braided, and the middle region (30) is a three-dimensionally braided tubular construct, the middle region (30) differs from the two end regions (22, 32) in size, braiding angle, porosity and mechanical strength. See Figure 2 and column 3, lines 1-27. This construction allows the prosthetic ligament (20) to be easily directed through a bore tunnel prepared in the femur and tibia and for the surgeon to impart the desired tension to the ligament with the ligament (20) securely fastened to the femur. See columns 3-4, lines 46-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Chervitz to modify the replacement ligament construct of Wolowacz et al. by including two end sections that are capable of attachment and a middle region differing from the two end regions in size, braiding angle, porosity and mechanical strength in order for the replacement ligament construct to be easily directed through a bore tunnel prepared in the femur and tibia and for the surgeon to impart the desired tension to the ligament with the ligament (20) securely fastened to the femur. As modified, the middle region of the replacement ligament construct of Wolowacz et al. will be capable of promoting the formation of ligament tissue.

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4. Claims 4, 5, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. in view of Chervitz as applied to claims 2 and 8 above, and further in view of Vacanti (USPN 5,855,610 as cited in previous office action).

Wolowacz et al., as modified by Chervitz, discloses a replacement construct for tendons or ligaments and a method of producing a graft material with all the elements of claims 2 and 8, including the cells being precursor cells to fibroblasts (page 2, lines 1-3), but is silent to the cells generating mesenchymal cells, as required by claims 4 and 10, and of the cells being pluripotent stem cells, as required by claims 5 and 11. Vacanti et al. teaches a replacement construct comprising a degradable, polymeric fiber-based, porous scaffold seeded with cells, wherein the cells are pluripotent stem cells because they are immunologically inert. See column 6, lines 50-53. It would have been obvious to one of ordinary skill in the art to modify the replacement construct of Wolowacz et al. by seeding the scaffold with pluripotent stem cells, which are cells that generate mesenchymal cells, because they are immunologically inert.

Response to Arguments

5. Applicant's arguments filed January 23, 2006 have been fully considered but they are not persuasive. Applicant argues that the examiner has failed to address the arguments and evidence set forth by the applicants in the last response which rebut any prima facie case of obviousness over the cited combination of prior art references. The examiner disagrees. In the office action mailed September 21, 2005, the examiner clearly addressed the arguments in paragraph 6 and the evidence paragraph 2.

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6. The examiner agrees that according to MPEP 2144.09, a prima facie case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. In order to do this, a declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art, which in this case is Wolowacz et al. See MPEP 716.02(e). Because the declaration filed on August 22, 2005 compares the subject matter to the secondary teaching reference of Chervitz, the declaration is insufficient to overcome the rejection. No other declaration has been filed to overcome the insufficiencies and meet the requirements.

7. In applicant's arguments and in Dr. Ko's declaration, reference is made to the experiments disclosed in the specification for providing as evidence. The fiber architecture of the three-dimensional braided scaffold of the present invention provides the scaffold with unexpectedly advantageous and superior properties with respect to cell in-growth, as compared to other scaffolds prepared from the same polymeric fibers. In particular, the comparison was made to a microfiber, non-woven mesh scaffold prepared from the same biodegradable polymeric fibers. These experiments, while proving unexpected advantage and superiority of the present invention over the other scaffolds in the experiments, do not provide as proof when comparing the claimed subject matter with the closest prior art. Because the scaffold of Wolowacz et al. is different from the "other scaffolds" of the experiments (Wolowacz scaffold is braided and the scaffolds in the experiments are non-woven mesh), one cannot presume that the results of the experiments would be the same when using the braided scaffold of Wolowacz. Therefore, the experiments are not related to the closest prior art and cannot be used as proof that

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the three-dimensional braided scaffold of the present invention has unexpectedly advantageous or superior properties over the closest prior art.

8. Applicant should keep in mind that in showing superior or unexpected results, proof must be provided that shows that the claimed compounds possess unexpectedly advantageous or superior properties. The unexpectedly advantageous and superior properties of the claimed invention are a result of the geometry of the scaffold and not of the compounds themselves. This is made evident in the experiments described in the specification, where scaffolds of the same material but different geometry and microstructure (three-dimensional braided scaffold versus non-woven mesh scaffold) result in different cell-growth. The declaration filed and arguments presented by applicant do not and cannot prove that the claimed compound possess unexpectedly advantageous or superior properties over the closest prior art because it does not.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

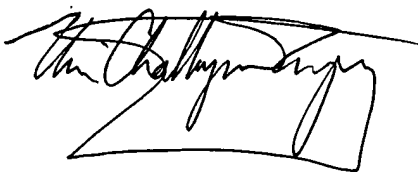
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner